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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,731	12/15/2003	Eberhard Weihe	029310.52995US	6798

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EXAMINER	
NICHOLS, CHRISTOPHER J	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,731	WEIHE ET AL.	
	Examiner	Art Unit	
	Christopher J. Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-15**, drawn to a method for detecting a pain-regulating substance using a recombinant cell, classified in class 435, subclass 7.1, for example.

II. Claims **16-17**, drawn to a *compound*, classification dependent upon compound structure.

III. Claims **18-20**, drawn to a method of alleviating pain, classification dependent upon the structure of therapeutic agent.

IV. Claims **21-26**, drawn to a method of providing gene therapy, classified in class 514, subclass 44, for example.

V. Claims **27-29**, drawn to a method of diagnosing a pain state, classification dependent upon the structure of diagnostic agent.

VI. Claims **30-32**, drawn to a method of detecting a pain-regulating substance comprising administering an effective amount of a diagnostic agent, classification dependent upon the structure of detection agent.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I, III, IV, VI, and VI are directed to different methods. Restriction is deemed proper because these methods constitute patentably distinct inventions for the following reasons: Inventions I, III, IV, V, and VI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of screening for a pain-regulating substance

using a recombinant cell, which is not required by any of the other Inventions. Invention III requires search and consideration of alleviating pain, which is not required by any of the other Inventions. Invention IV requires search and consideration of gene therapy for pain, which is not required by any of the other Inventions. Invention V requires search and consideration of diagnosing a pain state, which is not required by any of the other Inventions. Invention VI requires search and consideration of detecting a pain-regulating substance via administration of an agent, which is not required by any of the other Inventions.

4. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compound of Invention II could be made by materially different processes such as chemical synthesis or isolation from natural sources.

5. Inventions III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Invention II could be used in materially different processes such as identifying binding partners or biochemical assays.

6. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and V are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention V does not recite the use or production of the *compound* of Invention II.

7. Inventions V and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Invention II could be used in materially different processes such as identifying binding partners or biochemical assays.

8. Inventions VI and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Invention II could be used in materially different processes such as identifying binding partners or biochemical assays.

9. FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:

10. The inventions are distinct, each from the other because of the following reasons. The Inventions that are directed to <u>different</u> products, restriction is deemed proper because these products constitute patentably distinct inventions for the following reasons:

The sequences listed in the instant claims are distinct both physically and functionally, and are not required one for the other. Each sequence requires a separate non-overlapping search of the literature and sequence databases. A search and examination of an Invention as it pertains to all sequences would therefore present the examiner with an undue search burden.

11. Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect one group from I-VI. In order to be fully responsive, Applicant must elect one group from I-VI and one sequence from 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, and 14.

12. The Examiner notes that upon reaching allowable subject matter, rejoinder of sequences will be considered. To aid in examination and consideration of rejoinder, discussion or demonstration (through homology, for example) of related or "nested" sequences will greatly aid the Examiner in consideration of rejoining sequences upon reaching allowable subject matter.

13. **FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:**

14. The therapeutic agents listed in claims **18, 27, 30** are listed as an improper Markush Group. Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility [*In re Harnish*, **631 F.2d 716, 206 USPQ 300 (CCPA 1980)**; and *Ex parte Hozumi*, **3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984)**.]

15. The therapeutic agents, (a) polynucleotide, vectors and transformed host cells, (b) protein, (c) antibody, and (d) compound, do not share a common structure or function as

each agent is independent, distinct, and non-obvious over one another. Application is required to elect a single therapeutic agent because the agents are distinct both physically and functionally, and are not required one for the other. For instance methods using the first group are classified in 514/44, methods using proteins are generally classified in 514/2, methods using antibodies are generally classified in 424/130.1, and the classification of the final category depends upon the structure of the compound. As such each agent [(a) polynucleotide, vectors and transformed host cells, (b) protein, (c) antibody, and (d) compound] requires a separate search of the literature and patent databases. A search and examination of an Invention as it pertains to all agents would therefore present the examiner with an undue search burden as they occupy different states in the art and different classifications.

16. **Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect one group from I-VI. In order to be fully responsive, Applicant must elect one group from I-VI and one of the agents listed: (a) polynucleotide, vectors and transformed host cells, (b) protein, (c) antibody, or (d) compound.**

17. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

18. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

19. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

20. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

21. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
March 15, 2005